IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:	Barcelon et al.	)
Serial No.	09/092,696	)
Filed:	June 5, 1998	)
For:	ENHANCED FLAVORING COMPOSITIONS CONTAINING N-ETHYL-P-MENTHANE-3-CARBOXAMIDE AND METHOD OF MAKING AND USING THE SAME	))))

Declaration of Joan Harvey Pursuant to 37 C.F.R. §1.132

I, Joan Harvey, do hereby declare as follows:

1. As of the date of this Declaration, I am currently employed as the Director of Flavor Development and Emerging Science at Cadbury-Adams. Prior to such employment, I have been employed with AM Todd, David Michael & Co Inc, Hershey Foods Corp and Godiva Chocolatier. I have been working in the field of candy and flavor development for over twenty-five years. I received my Certification from the Society of Flavor Chemists in 1992 and have been a certified flavorist for over fifteen years. I received an Associate in Arts degree in chemistry from Penn State University in 1989 and I completed the Industrial Chemistry Certificate Program from Berks Technical Institute in 1980.

2. I have reviewed the Examiner's Office Action dated December 7, 2007, particularly the rejection of claims 14 and 18-20 of the subject application under 35 U.S.C. §103(a) over U.S. Patent No. 5,009,893 to Cherukuri et al. (hereinafter "Cherukuri"). I also have reviewed the Cherukuri patent, and specifically Example 3, Table V, which the Examiner has referred to in the Office Action.

3. Cherukuri is related to edible compositions, including confectionery compositions and chewing gums, that are capable of providing long-lasting breath freshening perception without bitterness. These compositions include menthol and an N-substituted-p-menthane carboxamide compound in specific amounts to achieve a heightened cooling sensation.

4. The subject invention is directed to chewing gums containing a fruit flavor and a low level of N-ethyl-p-menthane-3-carboxamide, which enhances the perception of the fruit flavor upon consumption. In particular, N-ethyl-p-menthane-3-carboxamide is present in an amount effective to enhance the fruit flavor, i.e., about 0.04% to about 2.2% by weight of the flavor composition.

5. I have reviewed Example 3 of Cherukuri, which is related to the preparation of confectionery compositions. Based on my understanding of the components and process described, hard candies were prepared. Four different confectionery compositions were prepared, the formulations for which are set forth in Table V of Cherukuri. Of these four confectionery compositions, only formulations 3 and 4 in Table V include a cherry flavor in combination with the cooling compound.

6. The cooling compound listed in Table 5 of Cherukuri is referred to as "Cooling Compound 2470". I am not aware of the specific chemical identity of this cooling compound.

7. If I were to attempt to develop chewing gums that are comparable to confectionery formulations 3 and 4 in Table V of Cherukuri, I would begin by modifying the types and amounts of a number of the components listed therein due to the vast differences in the two delivery systems. In particular, chewing gums and confectioneries, such as hard candies, are entirely different delivery systems. Confectioneries are water-soluble and designed to be fully consumed, whereas chewing gums are based on a portion that is insoluble and chewed rather than consumed. More specifically, chewing gums

include a gum base instead of the candy base listed in Table V. Unlike candy base, gum base is a highly water-insoluble substance, which forms the masticable portion of chewing gums. Gum base includes a number of materials that absorb various components, particularly flavors and actives. These components become entrapped in the gum base, thereby reducing the amount released during chew. Accordingly, the levels of such components often have to be increased when working with chewing gums as compared to confectionery products to achieve comparable effects. In addition to total flavor release concerns, individual components of the flavor release differently and therefore the flavor will taste different when incorporated into chewing gum with the result that the individual flavor components often have to be modified. These are just a few of the difficulties that arise when attempting to convert from a confectionery to a chewing gum delivery system.

8. These concerns are relevant for the cooling agent N-ethyl-p-menthane-3-carboxamide, also referred to as "WS-3". As indicated in the publication of N-ethyl-p-menthane-3-carboxamide on the FEMA-GRAS list in 1975 (a copy of which is attached hereto as Exhibit A), the recognized level of N-ethyl-p-menthane-3-carboxamide for use in hard candy is 100 ppm, whereas the recognized level of N-ethyl-p-menthane-3-carboxamide for use in chewing gum is 1200 ppm. The level recognized for use in chewing gum is 12 times higher than that recognized for use in hard candy. It is common practice in the industry to consult the FEMA-GRAS standards in developing consumable products including a listed component. Accordingly, I would use these FEMA-GRAS levels in attempting to develop chewing gums including N-ethyl-p-menthane-3-carboxamide. If I were to use N-ethyl-p-menthane-3-carboxamide as the cooling compound referred to in Cherukuri's Table V, then I would begin with the FEMA-GRAS levels in extrapolating confectionery formulations 3 and 4 of Table V into chewing gums.

9. Based on my experience, at the time of the subject invention, the flavor system in chewing gums typically was used at amounts of about 1-2% by weight of the chewing gum. In view of the FEMA-GRAS levels for N-ethyl-p-menthane-3-carboxamide

discussed above, I would use N-ethyl-p-menthane-3-carboxamide in amounts of about 1200 ppm in the chewing gums. 1200 ppm is 0.12% by weight of the chewing gum. The remainder of the flavor composition would include the other flavor components set forth in formulations 3 and 4 of Table V. Cherry flavor and eucalyptus oil would make up the remainder of the flavor composition for the chewing gum comparable to formulation 3. Cherry flavor, eucalyptus oil and menthol would make up the remainder of the flavor composition for the chewing gum comparable to formulation 4.

10. In such an extrapolation into chewing gums, therefore, N-ethyl-p-menthane-3-carboxamide would be present at the amount of 0.12% by weight of the chewing gum. The total flavor composition, of which N-ethyl-p-menthane-3-carboxamide is a part, would be present at amounts of 1-2% by weight of the chewing gum composition. If the minimum total flavor composition amount of 1% were used in the chewing gums, then N-ethyl-p-menthane-3-carboxamide would constitute 12% by weight of the flavor composition itself (0.12% of 1%). If the maximum total flavor composition amount of 2% were used in the chewing gums, then N-ethyl-p-menthane-3-carboxamide would constitute 6% by weight of the flavor composition itself (0.12% of 2%). Therefore, using typical flavor system levels in chewing gum would result in comparable chewing gum products that include anywhere from 6% up to 12% of N-ethyl-p-menthane-3-carboxamide by weight of the flavor composition. In accordance therewith, the remaining flavor components combined would be present at amounts from 88% up to 94% by weight of the flavor composition.

11. In sum, in attempting to extrapolate confectionery formulations 3 and 4 set forth in Table V of Cherukuri into chewing gums, there are a variety of modifications that must be made due to the differences in the two delivery systems. I would begin the development by incorporating the cooling agent N-ethyl-p-menthane-3-carboxamide in the accepted FEMA-GRAS levels for chewing gum. By using typical flavor system levels for chewing gum, N-ethyl-p-menthane-3-carboxamide thus would be present at amounts of 6-12% by weight of the flavor composition.

12. I have reviewed the claims of the subject invention directed to chewing gums including an enhanced fruit flavoring composition. It is my understanding that these claims require N-ethyl-p-menthane-3-carboxamide to be present at amounts of about 0.04% to 2.2% by weight of the flavor composition. The amounts of N-ethyl-p-menthane-3-carboxamide in the extrapolated chewing gums described herein, which are based on Cherukuri's Table V confectionery compositions, are substantially higher (6-12%) than that recited in these claims (0.04-2.2%). The higher amounts of N-ethyl-p-menthane-3-carboxamide in the extrapolated chewing gums are consistent with the teachings of Cherukuri because N-ethyl-p-menthane-3-carboxamide is being used in its conventional sense, to impart a cooling sensation. This is in contrast to the subject invention, which is using substantially lower levels of N-ethyl-p-menthane-3-carboxamide to enhance a fruit flavor perception, not for its cooling effects.

13. I hereby declare that all statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true; and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patents issued thereon.

Dated this 7 day of April 2008

Joan Harvey

EXHIBIT A

RIFM - FEMA Database

Skip To -

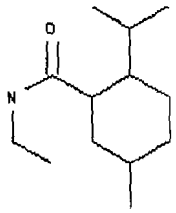
- Physical Data
- Flavor Consumption
- Food Uses
- Status
- Human Health Data
- Other References

Savvy Search

N-Ethyl-2-isopropyl-5-methylcyclohexane carboxamide

Comprehensive Computer Generated Synopsis

Synonyms	
Cyclohexanecarboxamine, N-ethyl-5-methyl-2-(1-methylethyl)-	CAS
N-Ethyl-2-isopropyl-5-methylcyclohexane carboxamide	Principal
N-Ethyl-2-isopropyl-5-methylcyclohexanecarboxamide	IUPAC
Ethyl menthane carboxamide	INCI
N-Ethyl-*p*-menthane-3-carboxamide	



Another Material

CAS Number	FEMA	EINECS	Registration
39711-79-0	3455	254-599-0	EINECS DSL TSCA

Formula $C_{13}H_{25}NO$ **Molecular Weight** 211.35

SMILES Notation O=C(NCC)C(C(CCC1C)C(C)C)C1

Generic Class (TSCA) Amines

Physical Data

Log K_{ow} (calculated)	3.81	Syracuse Research Corp.

Natural Occurrence	**N-Ethyl-2-isopropyl-5-methylcyclohexane carboxamide** has apparently not been reported to occur in nature.

Flavor Consumption (in kg)

1995	USA	966
1995	EUROPE	3.3
1987	USA	0.3
1982	USA	0

Uses (in ppm)

Product	Average Usual	Average Maximum	Mean Daily Consumption (gms)	Updated
Alcoholic Beverage	10	10	32.5	21-Feb-89
Baked Goods	10	10	137.2	21-Feb-89
Chewing Gum	1200	1200	0.2	21-Feb-89
Confection Frosting	10	10	0.3	21-Feb-89
Frozen Dairy	10	10	25.6	21-Feb-89
Fruit Ices	10	10	0.7	21-Feb-89
Hard Candy	100	100	0.6	21-Feb-89
Jam Jelly	10	10	5.7	21-Feb-89
Non-alcoholic Beverage	10	10	104.0	21-Feb-89
Soft Candy	10	10	5.8	21-Feb-89

PADI 3.41

Status

N-Ethyl-2-isopropyl-5-methylcyclohexane carboxamide was included by the Council of Europe in the list of substances granted B - information required - mutagenicity studies (COE No. 2298)

Flavor and Extract Manufacturers' Association: Generally Recognized as Safe as a flavor ingredient - GRAS 9. (3455) Oser,1975

Joint Expert Committee on Food Additives: The Joint FAO/WHO Expert Committee on Food Additives (JECFA) concluded that the substance does not present a safety concern at current levels of intake when used as a flavouring agent. (1601)

JECFA Specification Website

Human Health Data

Other References to N-Ethyl-2-isopropyl-5-methylcyclohexane carboxamide

RIFM - FEMA Database

Evaluation Priorities

DCN.TREE	3	1-Apr-89
ICFPS	3	3-Dec-91
REDBOOK	3	1-Apr-89